

REMARKS

Applicants respectfully request reconsideration of the application in view of the following remarks.

Claims 1-13 are pending in the application, with claims 1, 7, and 12 being independent claims. Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/19186 ("the Sun PCT") in view of U.S. Patent No. 5,661,170. This rejection is respectfully traversed.

Applicants would like to thank the Examiner for courtesies extended during a telephone conversation with Applicants' undersigned attorney on October 17, 2005. As agreed during the conversation, Applicants now present the following remarks in further explanation of the claim amendments made in the Amendment of May 13, 2005.

In the Amendment filed May 13, 2005, independent method claims 1 and 7 were amended to recite, in part, "administering to a nail area of a patient a composition that is effective for treating onychomycosis and that *comprises urea as the sole active antifungal ingredient.*" Independent method claim 12 was amended to read "administering to a nail area of a patient a composition *comprising urea as the sole active antifungal ingredient.* . . wherein the urea is present in an amount therapeutically effective for treating onychomycosis."

In contrast to the claimed invention, the Sun PCT teaches using urea as a permeation enhancer to enhance permeation of an antifungal agent, such as itraconazole, ketoconazole, or miconazole nitrate. Urea is not even listed among "antifungal drugs that can be used in the invention" described in the Sun PCT (page 7, line 35 to page 8, line 5). The Sun PCT states that "urea's principal contribution to the efficiency of the formulation used in the invention is to inhibit the nail keratin from returning to its original densely packed cross-linked state. . . so that the nail remains more permeable to the antifungal drug over a longer period of time" (page 8, lines 17-23).

Each of “representative formulations” A through F and H through L in the Sun PCT includes, in addition to urea, one of the “preferred” antifungal drugs miconazole nitrate and itraconazole. One “representative formulation,” formulation G, contains the preferred antifungal drug miconazole nitrate but no urea. Formulation G is meant to be used after the nail has been pre-treated with urea, and there is no teaching or suggestion that such pre-treatment is, in itself, effective for treating onychomycosis. Nowhere in the Sun PCT is there a recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis. The Sun PCT explicitly discloses many antifungal drugs that are all different from urea, and that urea is present to enhance permeation of these different antifungal drugs through nail tissue.

Thus, in contrast to the claimed invention, the Sun PCT does not teach or suggest urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis, or that the urea is present in an amount therapeutically effective for treating onychomycosis.

In the Final Office Action, the Examiner states that “the ‘comprises’ language. . . allows the presence of additional ingredients, that is to say, that while Sun administers these ingredients (i.e. itraconazole, ketoconazole or miconazole nitrate), the ‘comprises’ language opens up the composition to include these ingredients and the claim does not exclude these ingredients.”

Applicants agree that the use of the word “comprises” in claims 1 and 7 and “comprising” in claim 12 does allow the presence of ingredients additional to those specifically identified in those claims. As described in the specification, compositions employed in methods of the present invention can include, for example, petrolatum, mineral oil, fatty alcohols or acids, glyceryl stearate, xanthan gum, carbomers, and triethanolamine. Such ingredients are not excluded by the language of the independent claims. However, the plain language of the independent claims indicates that no active antifungal ingredient besides urea can be present in the compositions employed in methods of the claimed invention. Applicants submit for the record that the language “urea as the sole active antifungal ingredient,” found in each of the

independent claims, means that urea is the only active antifungal ingredient present in the compositions administered in methods of the claimed invention, and that all active antifungal ingredients besides urea are excluded by the claims.

Thus, the language “urea as the sole active antifungal ingredient” excludes itraconazole, ketoconazole, miconazole nitrate, and any of the other “antifungal drugs” listed in the Sun PCT from compositions employed in methods of the present invention. Applicants submit that the independent claims patentably distinguish the present invention over the Sun PCT due to recitation of administering “a composition that is effective for treating onychomycosis and that comprises urea as the sole active antifungal ingredient” (claims 1 and 7) or administering “a composition comprising urea as the sole active antifungal ingredient. . . wherein the urea is present in an amount therapeutically effective for treating onychomycosis” (claim 12).

Additionally, Applicants submit that the Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis. The Chodosh patent merely discloses that “imidazolidinyl urea” and “diazolidinyl urea” are “common preservatives” (col. 6, lines 6-8 and col. 7, lines 8-9). As shown in Tables 2 and 3 of the Chodosh patent, diazolidinyl urea may be present in amounts of up to 1.0 wt%. Nowhere in the Chodosh patent is there any mention of “urea” as opposed to the preservatives “imidazolidinyl urea” and “diazolidinyl urea,” much less any mention of urea as an effective antifungal ingredient. Thus, the independent claims patentably distinguish the present invention over the Sun and Chodosh documents, whether those documents are taken individually or in combination.

In the Office Action, the Examiner also states that “since the urea in the claim is effective for treating onychomycosis, then urea in the Sun reference should provide the same results.” Applicants respectfully submit that it is improper to look to the present application to find a reasonable expectation of success and to use such finding as a basis for rejecting the present claims under 35 U.S.C. § 103(a). Neither the Sun PCT nor the Chodosh patent would have caused one of ordinary skill in the art to think that urea could be used as the sole active

antifungal ingredient in a composition therapeutically effective for the treatment of onychomycosis. It is the present application which teaches that urea can be so used and result in effective treatment of onychomycosis.

For the above reasons, Applicants submit that the § 103(a) rejection of the independent claims cannot properly be maintained. The dependent claims are also submitted to be patentable, for the same reasons that the base claims from which they depend are patentable, and further due to the additional features that they recite. Individual consideration of each dependent claim is respectfully requested.

Information Disclosure Statement

Attached to the Office Action was a Form PTO/SB/08a/b from an Information Disclosure Statement filed on January 14, 2004. The form was initialed and signed on July 15, 2005 by the Examiner to indicate consideration of documents listed on the form. However, a line was drawn through citation "CF" on the form (referring to "U.S. Patent Application Serial No. 09/998,537, filed November 28, 2001 entitled 'Antioxidant Dermatological Composition'"), indicating that citation CF was not considered. During a telephone conversation with Applicants' undersigned attorney on October 24, 2005, the Examiner reviewed the Form PTO/SB/08a/b and stated that citation CF should have been considered.

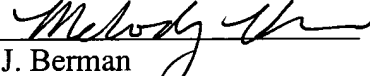
A copy of page 2 of the Form PTO/SB/08a/b, showing a line drawn through citation CF, was faxed to the Examiner on October 24, 2005, together with a request that the Examiner indicate consideration of citation CF. For the Examiner's convenience, Applicants herewith enclose a copy of page 2 of the Form PTO/SB/08a/b as filed on January 14, 2004, which does not have a line drawn through citation CF. Applicants respectfully request that the Examiner indicate consideration of U.S. Patent Application No. 09/998,537 by signing and returning a copy of page 2 of the Form PTO/SB/08a/b on which citation CF has been initialed.

Applicants believe that a full and complete response has been made to the outstanding Office Action and that, as such, the present application is in condition for allowance. If the

Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

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Respectfully submitted,

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